

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

		Date of mailing (day/month/year) 01 NOV 2005
Applicant's or agent's file reference S.V.SE. LTD		FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/IL05/00218	International filing date (day/month/year) 23 February 2005 (23.02.2005)	Priority date (day/month/year) 24 March 2004 (24.03.2004)
International Patent Classification (IPC) or both national classification and IPC IPC(7): A61B 17/04 and US Cl.: 227/175.1		
Applicant SHIFRIN, EDWARD G.		

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Glenn K. Dawson Sheila H. Veney Paralegal Specialist Telephone No. 703-308-0858 Tech. Center 3700
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

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Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 - a sequence listing
 - table(s) related to the sequence listing
 - b. format of material
 - in written format
 - in computer readable form
 - c. time of filing/furnishing
 - contained in international application as filed.
 - filed together with the international application in computer readable form.
 - furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-27	YES
	Claims <u>NONE</u>	NO
Inventive step (IS)	Claims 1-27	YES
	Claims <u>NONE</u>	NO
Industrial applicability (IA)	Claims 1-27	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-27 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method of intraluminally fixing an intravascular device including attaching an intravascular device to a stapler; creating a duct to access a lumen of a vessel, inserting the stapler through the duct into the vessel, generating radial forces upon fastener means in a radial direction to puncture the wall of the intravascular device and vessel wall such that the ends of the fastener are bent over the outer surface of the vessel wall to rigidly connect the 1st end of the device to the vessel wall; removing the stapler from the vessel; making an incision in the device for access to its lumen; inserting another stapler through the duct and incision into the lumen of the device; generating radial forces to radially deliver fasteners through the device and through the vessel wall such that ends of the fastener are bent over the outer surface of the vessel wall; removing the 2nd stapler and closing the incision and duct whereby multiple-spot connections are formed to secure the device to the vessel.

Also not disclosed or suggested is a stapler having a tubular body, a head with a die and die lid coaxial with the head and each other; the die receiving fasteners and having a cylindrical generatrix and inner axial cavity, the bottom of the cavity having a hole through evenly arranged radial slots; the die having recesses with grooves for receiving staple fasteners on an end face facing the die lid; the recesses are coaxial with the slots and have means for setting apart the ends of the staple fasteners disposed along axes of the grooves adjacent the generatrix of the die and are v-shaped; the die lid has a hole, a cylindrical generatrix, proximal and distal end faces slots and means for retaining the ends of the staples and means for separating the middles of these staples disclosed near the intersection of the radial slots with the distal end face of the die lid; a control mechanism, a pressure rod; means for transmitting axial force from the rod to the staples and for transmitting axial force to radial force, and means for temporarily fixing the intravascular device to the stapler.

Claims 1-27 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

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Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

The specification and claims contain numerous typographical and syntax errors. A few examples are found in claim 1 line 2, "substantilly" and in line 8, "deyece". The entire application should be reviewed and corrected.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 1-27 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because claims are indefinite for the following reason(s): in claim 1, the use of "substantially grafts or stent-grafts" is indefinite in that it is unclear if the claims are limited to such. It is unclear to what the device corresponds in line 6. there is no antecedent basis for "the body" in line 5. In step d it is unclear what stapler is being referenced since two have been previously recited. In step e, there is no antecedent basis for "the actuator". In step m, it would appear as if a 3rd stapler is being introduced, however, this is not clear. In claim 10, step iii, it is not clear if a 2nd die is being recite. In step iv it is unclear if a 2nd die lid is being recited.